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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/621,972

07/17/2003

Ross S. Tsugita

1001.1421103

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/621,972

**Applicant(s)**

TSUGITA, ROSS S.

**Examiner**

Eric Blatt

**Art Unit**

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-77 is/are pending in the application.
- 4a) Of the above claim(s) 72-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-15-2008 has been entered.

### ***Election/Restrictions***

Newly presented claims 72-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election Invention I drawn to a medical device was made without traverse in the reply filed on Oct. 10, 2006.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53-58, 60-65, and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028).

Gray discloses guidewire 30, filter 50 and stent (page 6, lines 15-17). Gray fails to disclose a first shaft (claim 32) or outer catheter shaft (claim 41) with a balloon coupled thereto. However, Patel teaches that a guiding catheter 11 with a balloon 25 should be used with a dilating catheter 29 in order to obtain the advantage of guiding the dilating catheter 29 within the vasculature while the balloon 25 holds the guiding catheter in place (col. 1, lines 43-52 and col. 3, lines 15-27). It would have been obvious to use a guiding catheter with a balloon with the Gray dilating catheter so that it too would have this advantage. The guiding catheter is the claimed "first shaft" (claim 32) or "outer catheter shaft" (claim 41). As to claims 33 and 38, Gray fails to disclose that the stent is self expanding and is retained in a collapsed configuration by a retaining sleeve. However, it is old and well known in this art to make stents self-expanding in order to obtain the advantage of enabling them to automatically expand when released by the retaining sleeve. It would have been obvious to make the Gray stent self expanding so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). Alternatively, it would have been obvious to use the first catheter as a retaining sheath for the stent since deployment systems wherein a stent is held between an inner and an outer catheter were also notoriously old and well known in the art.

Applicant has previously argued that the guiding catheter 11 and balloon 25 of Patel are not configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded because the guide catheter 11 comprises port 27 which allows some quantity of blood to flow into the lumen of guide catheter 11 and to perfuse out of the tip 21. In response, Examiner first notes that the language requires only that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft from flowing distally past the distal region of the shaft. Blood that flows into port 27 is not outside of the first catheter shaft. Moreover, looking to Applicant's current claims 63 and 64, Applicant has claimed precisely such an infusion port in combination with the limitation that the balloon and catheter are capable of preventing flow past the balloon. From this, it appears that Applicant does not consider the existence of an infusion port proximal to the balloon to exclude the prevention of fluid flow as claimed.

Regarding claims 60-65, Patel teaches that oxygenated blood flows through an infusion port proximal to the balloon and perfuses out the distal end of the guiding catheter. The perfusion lumen is inherently capable of directing the perfusing fluid at an inner surface of a body lumen. Since the perfusion lumen will be positioned within a body lumen, literally any direction will be toward an inner surface of the body lumen.

Claims 59, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028) as applied to claims 53 and 56 above, and further in view of Dubrul (US 6,258,115).

Regarding claim 59, Dubrul teaches that it was known for self expanding stents to be thermally activated. (Column 9, Lines 59-60) It would have been obvious to one of ordinary skill in the art to use a thermally activated self-expanding stent since such stents were well known alternatives to the balloon expandable stents discussed in Gray and this substitution would not have produced unexpected results.

Regarding claims 66 and 67, Dubrul teaches providing an stenting and distal protection system with an aspiration device so that dislodged emboli can be aspirated from the vessel prior to un-deploying the filter and removing it. It would have been obvious to one of ordinary skill in the art to modify the system taught by Gray in view of Patel by providing an aspiration catheter in order to remove debris from the vessel and filter while the filter is disposed in the lumen as taught by Dubrul. Further, it would have been obvious to size the aspiration catheter such that it is capable of being slidably disposed in the first catheter shaft in order to allow the aspiration catheter to easily reach the procedure site.

### ***Double Patenting***

Claims 32-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,168,579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the small differences in the wording between the sets of claims do not define significant, non-obvious distinctions.

***Response to Arguments***

Applicant's arguments with respect to claims 53-71 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

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Eric Blatt

571-272-9735